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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,495	12/30/2004	Ingela Petersson	0104-0497PUS1	5386

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EXAMINER

MAI, HAO D

ART UNIT	PAPER NUMBER
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3732

NOTIFICATION DATE	DELIVERY MODE
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12/16/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/519,495	Applicant(s) PETERSSON ET AL.	
	Examiner HAO D. MAI	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,7-11,13,14 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,7-11,13,14 and 16-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/03/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 1-3, 7-8, 11, 13-14, and 17-24, are rejected under 35 U.S.C. 102(b) as being anticipated by Leitao (6069295).**

Regarding claim 1, Leitao discloses an implant and method for treating the implant surface with hydrofluoric acid in order to provide a roughness of pores and peaks to the implant surface (column 2 lines 49-51). Leitao discloses the implant made of titanium material and having average peak distance, i.e. the pore diameter, to be from which covers the claimed range of $\leq 1 \mu\text{m}$. The pore depth is disclosed to be from $.02 \mu\text{m}$ - $2 \mu\text{m}$ which covers the claimed range of $\leq 500 \text{ nm}$ ($0.5 \mu\text{m}$). Leitao teaches of an average peak distance and uniform result (column 2 lines 56-57); thus it is inferred that the peak width, at half the pore depth, is generally equal to, e.g. within the range of 15 to 150% of, the pore diameter. Leitao however is silent to the concentration of the hydrofluoric acid being less than 0.5 M. Nevertheless, such range of concentration would have been obvious since it would have been obtainable by a person of the ordinary skill in the art via routine experimentation in order to obtain the optimum results.

As to claim 2, the claimed ranges of 50 nm to $1 \mu\text{m}$ for pore diameter, and 50 – 500 nm for pore depth, each falls within the disclosed respective ranges of $0.01 \mu\text{m}$ to $0.2 \mu\text{m}$ (column 1

Art Unit: 3732

lines 52-53) and .02 μm - 2 μm (column 1 lines 60-62). As to claim 11, the implant is disclosed to be made of titanium.

As to claims 3 and 7-8, Leitao is silent to the various ranges of the root-mean-square roughness, the concentration of the hydrofluoric acid, and the period of time of treating/etching. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make an implant with a surface roughness with the claimed range of root-mean-square roughness, concentration of the hydrofluoric acid, and the period of time of treating/etching because: (1) such ranges are well within the skill of an artisan obtained via routine experimentation in order to achieve optimum results; and (2) differences in such ranges will not support the patentability of the subject matter encompassed by the prior arts unless there is evidence indicating such measurements are critical. MPEP §§ 2144.05.

Regarding claim 13-14 and 17-20, Leitao disclose all the claimed elements as detailed above with respect to claims 1-3, 7-8, and 11. As to claims 21-24, such claimed ranges of the peak width as half the pore depth would have been obvious to one having ordinary skill in the art obtainable via routine experimentation. MPEP §§ 2144.05.

3. Claims 9-10 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leitao) in view of Hama et al. (4,818,559).

Leitao discloses the invention substantially as claimed except for providing a macro-roughness by blasting the surface prior to providing the micro-roughness. Hama et al. disclose providing a macro-roughness to an implant surface by blasting the surface prior to chemical treating/etching (column 3 lines 55-59). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Leitao by providing a macro-roughness

Art Unit: 3732

by blasting prior to chemical treating/etching the implant surface in order to provide a better adhesion between the core and the coating layer as explicitly taught by Hama et al.

Response to Arguments

4. Applicant's arguments filed 07/11/2008 have been fully considered but they are not persuasive. Leitao discloses the implant with a surface roughness as claimed, and that such surface roughness is obtained by treatment with hydrofluoric acid (see rejection above). However, Applicant argued that Leitao does not teach of treatment with hydrofluoric acid being less than 0.5 M and that such concentration is critical in providing the claimed surface roughness. The Examiner maintains that such range of concentration of the hydrofluoric acid (HF) is obvious because it would have been obtainable by a person of ordinary skill in the art via routine experimentation. The reasoning is that if the claimed surface roughness is provided by treatment with HF as disclosed by Leitao, then the claimed critical range of concentration of HF must be obtainable in view of Leitao, albeit via routine experimentation, in order to provide said disclosed surface roughness.

Regarding rejection under Leitao in view of Hama, Applicant argued that Hama teaches of macro-roughness, not micro-roughness. Note that Hama is relied upon for rejection of claims 9-10 and 16 which claim a macro-roughness surface.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing

Art Unit: 3732

date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAO D. MAI whose telephone number is (571) 270-3002. The examiner can normally be reached on Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached at (571) 272-4922. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/Hao D Mai/
Examiner, Art Unit 3732**

**/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732**